# The New Hampshire Department of Health and Human Services

## Adverse Event Reporting Form

1. **Is the event being reported SERIOUS and UNEXPECTED occurring at the PI's site** ☐ **YES** ☐ **NO**
2. **Is this an adverse event that is serious, unexpected, probably or definitely related to study procedures and occurred at a site other than the PI's?** ☐ **YES** ☐ **NO**

**Serious** - Resulted in death; was life threatening; required or prolonged an existing hospitalization; resulted in persistent or significant disability or incapacity; resulted in a congenital anomaly or birth defect; resulted in cancer; or any medical event which requires medical treatment to prevent one of the medical outcomes listed above.

Unexpected - An event that is inconsistent with the frequency, nature, or severity of the event as documented in the consent form and is not considered to be a known risk or complication of the illness under study

**If yes to either 1 or 2,** complete this form and forward with appropriate attachments to the CPHS
**If no**, do not forward to the CPHS but report to sponsor and/or FDA as required.

**Please be sure all identifying information (pt. name) is blacked out from all pages.**

Date: _____ CPHS #: _____

Investigator: _____

Study Title: _____

_____

**1. Adverse Event (e.g., myocardial infarction):**

_____

**Please indicate severity** (select one)**:**

- **a.** ☐ **Moderate** (discomfort enough to interfere with usual activity)
- **b.** ☐ **Severe** (incapacitated to work or to do usual activity, required hospitalization)
- **c.** ☐ **Fatal**

**Please provide a brief summary (attach sheet if necessary) of the circumstance of the event (include a copy of all notifications and/or letter of adverse event from the study sponsor or other sites). Include actions taken to remedy the situation.**

**2. Please provide a brief statement as to whether, in your judgment, the event was caused by the therapy or procedures associated with this protocol**.

**Select one:** ☐ Not related ☐ Unlikely ☐ Possibly ☐ Probably ☐ Definitely related

**3.** Is the risk of this AE contained in the consent form? ☐ **YES** ☐ **NO**
**4.** Is the risk of this AE contained in the investigators brochure (IB)? ☐ **YES** ☐ **NO**

**5. Should the informed consent, or any other portion of the study be modified as a result of this event? _____**
**If yes, please enclose modified documents, with all modifications in bold print, or highlighted.**

**6. Should/will currently enrolled individuals be notified of this event? _____**
**If yes, describe method of notification:**

**Signed: _____ Date: _____**
**(Principal Investigator)**

**Print Before Closing**